

conducted in health maintenance organizations were more likely to have a PSA-screening, compared to physician group settings. General practitioners were more likely to receive PSA-screening compared to other types of specialists. Interactions between race and insurance type were not significant. **CONCLUSIONS:** Hispanics and individuals insured by Medicaid are less likely to receive PSA-screening during an ambulatory care office-visit for a PHE. Efforts to improve access to cancer-screening services are warranted for these groups. It is necessary to consider the differential impact of PCa-screening policies on medically underserved populations.

**PCN184****CANCER CARE COSTS TREND IN THE UNITED STATES: FINDINGS FROM THE MEDICAL EXPENDITURE PANEL SURVEY 2008-2011**Haider MR<sup>1</sup>, Qureshi Z<sup>1</sup>, Salloum R<sup>1</sup>, Heidari K<sup>2</sup>, Xirasagar S<sup>1</sup>, Bennett C<sup>1</sup>, Khan MM<sup>1</sup><sup>1</sup>University of South Carolina, Columbia, SC, USA, <sup>2</sup>Department of Health and Environmental Control, Columbia, SC, USA

**OBJECTIVES:** To estimate the annual financial burden of cancer care in the United States and to study the effects of cancer on total health care of the country. **METHODS:** Direct medical cancer care costs of for the years 2008-2011 were estimated using the household component of the Medical Expenditure Panel Survey (MEPS), a nationally representative survey that includes self-reported health care utilization and expenditures for the US civilian non-institutionalized population. The likelihood of having a cancer diagnosis by age, race and insurance status and other variables were also assessed. **RESULTS:** Aggregate cost of cancer in the US increased from \$183 billion in 2008 to \$236 billion in 2011. While total out-of-pocket (OOP) costs per cancer case decreased from \$1,419.43 in 2008 to \$1,254.77 in 2011, total cost per-case increased from \$10,461.66 to \$12,583.69 over 2008 to 2011. The OOP and total medical care expenditures per case in 2008 were \$1,560.54 and \$11,501.69 respectively in 2011 prices using Urban Medical Consumer Price Index. OOP per case declined at an annual rate of 7.3% while the total direct cost increased at an annual rate of about 3%. Whites, females and 45-64 year olds were more likely to have a cancer diagnosis and most cancer care costs were covered by private insurers. Geographical location was not associated with cancer diagnosis although the southern region has the highest concentration. **CONCLUSIONS:** Our study confirms that cancer is a significant cost driver of the US health care system. Due to expected increase in the number of incident cases and survival rate, total cost of cancer is likely to increase rapidly over the next decade. With the implementation of the Affordable Care Act, burden of cancer care costs on taxpayers will increase due to higher insurance coverage and lower OOP cost.

**PCN188****AN ONLINE PATIENT-ORIENTED RADIATION RISK ASSESSMENT TOOL TO PROJECT CANCER RISK FOLLOWING EXPOSURE TO LOW-IONIZING RADIATION IN CANADA**

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**OBJECTIVES:** Increasing use of imaging procedures has raised concerns about the risk of cancer due to repeated exposure to low-ionizing radiation. We developed an online radiation risk assessment tool to project the lifetime attributable risk (LAR) of cancer incidence following repeated exposure to imaging procedures. **METHODS:** We developed a risk projection model to assess radiation exposure from imaging procedures, to estimate the lifetime attributable risk (LAR) of cancer incidence and 95% uncertainty limits (UL), according to age, gender, and imaging type. We used the "linear no-threshold" models (extrapolation of risk associated with high-dose ionizing radiation to low-dose exposure). The model has been adjusted using Canadian data to reflect the Canadian population. **RESULTS:** Selected simulation results are presented. The LAR of cancer incidence for a 50 and 70 year old male, exposed to a single coronary angiogram is 11 (95% UL: 6-22) and 6 (3-12) per 10,000 exposed, respectively. As the number of coronary angiograms increased from one to five over time, the cancer risk increased to 54 (27-106) and 26 (14-52) per 10,000, respectively. As age increases the excess lifetime risk of cancer decreases. The excess lifetime risk of cancer is higher for females than for males. The LAR of cancer for a 70 year old male and female, exposed to a computed tomography (CT) for suspected stroke is 4 (2-8) and 5 (3-10) per 10,000, respectively. As the number of CT scans increased from one to five, the total risk of cancer increased to 17 (8-33) and 23 (12-43) per 10,000, respectively. **CONCLUSIONS:** Patients are rarely aware of radiation risk. Physicians often underestimate the magnitude of radiation doses arising from imaging procedures. An online, interactive model might facilitate the decision making process, leading to more informed decisions and improved clinical outcomes.

**PCN189****REIMBURSEMENT RECOMMENDATIONS FOR CANCER PRODUCTS WITHOUT STATISTICALLY SIGNIFICANT OVERALL SURVIVAL DATA: A REVIEW OF CANADIAN PCODR DECISIONS**Heyland K<sup>1</sup>, Samjoo IA<sup>2</sup>, Grima DT<sup>1</sup><sup>1</sup>Cornerstone Research Group, Burlington, ON, Canada, <sup>2</sup>Cornerstone Research Group Inc., Burlington, ON, Canada

**OBJECTIVES:** Overall survival (OS) data for cancer products is an important endpoint to payers. This study sought to examine (1) what proportion of positive reimbursement recommendations by the pan-Canadian Oncology Drug Review (pCODR) occurred despite unavailable statistically significant overall survival data, and (2) the proportion of negative recommendations that noted a lack of overall survival data as a contributing factor. **METHODS:** Recommendations publicly accessible at [www.pcodr.ca](http://www.pcodr.ca) and [reimbursementdecisions.com](http://reimbursementdecisions.com) were reviewed for the period 13 July 2011 - 9 December 2013. **RESULTS:** During this time period, 28 submissions containing 32 oncology-specific indications were deliberated on by the pCODR committee. Of the eight indications that received a negative recommendation, only one had statistically significant overall- and progression-free survival data. A total of 24 indications received positive recommendations. Of these, two were based on single-arm Phase II clinical trials. The remaining 22 positive recommendations were based on

randomized controlled trials (RCTs), with 19 including OS as an endpoint. Seven of these 19 indications had statistically significant OS data based on the most recent data cut included in the manufacturer's submission to pCODR, while the remaining 12 either did not have statistically significant OS data or the OS data were immature (i.e., median OS not yet reached) at the time of submission. More than half of the 12 submissions with non-significant OS trial data allowed cross-over in the trial (n=9) thereby potentially confounding the clinical benefit of the active therapy. Of the 19 positive recommendations which had an RCT design and assessed OS as an endpoint, progression-free survival (PFS) was statistically significant with or without additional clinically or statistically significant secondary endpoints. **CONCLUSIONS:** This study highlights that positive pCODR recommendations may be made in the absence of a clear OS benefit, provided strong PFS and/or additional endpoint data exist.

**PCN190****INSIGHTS INTO THE PAN-CANADIAN ONCOLOGY DRUG REVIEW RECOMMENDATIONS - THREE YEARS AFTER ITS INCEPTION**Samjoo IA<sup>1</sup>, Grima DT<sup>2</sup><sup>1</sup>Cornerstone Research Group Inc., Burlington, ON, Canada, <sup>2</sup>Cornerstone Research Group, Burlington, ON, Canada

**BACKGROUND:** In 2010, the permanent national oncology-specific drug review process, pan-Canadian Oncology Drug Review (pCODR), was established to assess the clinical evidence and cost-effectiveness of new cancer drugs and provide recommendations to the provinces (except Quebec) and territories to guide their drug funding decisions. **OBJECTIVES:** This study sought to identify characteristics and decision patterns of the pCODR recommendations. **METHODS:** Twenty-eight recommendations, covering 33 requested populations, publicly accessible at [www.pcodr.ca](http://www.pcodr.ca) were reviewed since pCODRs operation: 13 July 2011 - 9 December 2013. Additional information was obtained from the [www.reimbursementdecisions.com](http://www.reimbursementdecisions.com) database. **RESULTS:** Of the twenty-four positive recommendations for coverage, three suggested a more limited patient population than the one requested. Four population funding requests received positive recommendations for the requested population without conditions. In seventeen cases, positive recommendations for the requested population were made conditional on improvement of cost-effectiveness ratios. Nine negative recommendations were made due to: a) limitations in evidence from phase two trials; b) modest progression-free survival, lack of statistically significant overall survival, lack of quality of life data and poor cost-effectiveness, and/or; c) unclear clinical benefit and an unacceptable cost-effectiveness model. Many economic reviews by pCODR included re-analyses of the cost-effectiveness ratios which in some cases had substantial impact on cost-effectiveness. The most common changes from the submitted analyses where limiting product benefit post-progression, time horizon reductions, or changes to post-progression mortality risk. **CONCLUSIONS:** Most submissions resulted in a positive funding recommendation. The positive conditional pCODR recommendations support a continued provincial product listing agreement structure that includes rebates to lower cost-effectiveness. The economic re-analyses of the post-progression survival benefit indicates a need for manufacturers to provide comprehensive consideration of uncertainty surrounding such benefits in the submitted cost-effectiveness analysis.

**PCN191****LESSONS FOR ADAPTIVE LICENSING: ANALYSIS OF CONDITIONALLY APPROVED EMA COMPOUNDS, THEIR REIMBURSEMENT STATUS AND REGULATORY/REIMBURSEMENT DATA REQUIREMENTS**

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**OBJECTIVES:** Understand how conditionally approved (CA) compounds in the EMA have performed in reimbursement assessment. Findings will inform current adaptive licensing initiatives. **METHODS:** EMA EPAR reports were analysed to identify CA compounds from 2006-2013. HTA reports from national reimbursement authorities of the UK (NICE, SMC), France (HAS), Germany (G-BA) and Italy (AIFA) were also analysed to understand reimbursement status of these products. **RESULTS:** 20 CA compounds were identified: 11 with current CA status, 7 fully approved and 2 withdrawn. Approval was based upon strength of clinical data from PII/PIII studies. In France, 86% of CA indications were reimbursed, most with an ASMR V. In Italy, 62% of CA indications were reimbursed. Risk sharing agreements (RSA) were used in at least 38% of approvals. In Germany, approximately 50% of CA products licensed after AMNOG were reimbursed. In the UK, only 6 CA products received a positive NICE recommendation, 5 under RSAs to fulfil the cost-effectiveness criteria. CA is granted on limited clinical evidence. Countries using a therapeutic-benefit assessment (e.g. France) reimbursed more CA compounds than cost-effectiveness (CE) driven countries (e.g. UK). RSA is a key tool to win reimbursement in cost-effectiveness countries where high ICER thresholds impeded reimbursement (Bosutinib) or insufficient clinical data (Pixantrone). Positive reimbursement decisions were driven by robust clinical data in orphan or small indications with limited therapies. Strategies employed by companies to overcome payer concerns include: 1) Initial restriction of compound approval to small high unmet need subpopulations; 2) Performance or financial risk sharing arrangements; 3) On-going evidence development plans. **CONCLUSIONS:** Reimbursement outcomes for CA compounds are variable across the EU. This is due to either clinical or economic uncertainties from evidence produced. To deal with these uncertainties, agreed mechanisms for continual evidence development and RSA implementations should be incorporated into on-going adaptive licensing initiatives.

**PCN192****CORRELATION OF HTA DECISION OUTCOMES IN FRANCE AND GERMANY**Sun D<sup>1</sup>, Beckerman R<sup>1</sup>, Bustamante MMD<sup>2</sup><sup>1</sup>CBPartners, New York, NY, USA, <sup>2</sup>CBPartners, Basel, Switzerland

**OBJECTIVES:** The objective of this study is to compare the HTA decisions of oncology products in France and Germany and provide insight into the most important asset value attributes that characterise a positive appraisal in these markets. **METHODS:** We analysed the G-BA and the HAS assessments of 11 oncology products published